



Atty. Docket No.: 25436/2422

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Happe, et al.  
Serial No.: 10/820,971  
Filed: April 8, 2004  
Entitled: METHODS AND COMPOSITIONS  
FOR THE DETECTION OF  
BACTERIAL SPECIES

Examiner: Not Yet Assigned  
Group Art Unit: 1645  
Conf. No.: 9749

**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8a**

I hereby certify that this correspondence (and any paper or fee referred to as being enclosed) is being deposited with the United States Post Office as First Class Mail on the date indicated below in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Brenda M. Woods

Name of Person Mailing Paper

Signature of Person Mailing Paper

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §§ 1.56, 1.97 AND 1.98**

Dear Sir:

In accordance with the duty of disclosure under 37 CFR § 1.56, Applicant submits this Information Disclosure Statement pursuant to 37 CFR §§ 1.97 and 1.98 in the above-identified application for consideration by the Patent Office.

A listing of the cited documents, as well as, for the Examiner's convenience, copies of all foreign patent documents and non-patent literature are enclosed. This application was filed after June 30, 2003, and copies of U.S. patents and U.S. patent applications are not required and are not enclosed.

Pursuant to CFR § 1.97(b)(3), because this Statement is being submitted before the first Office Action on the merits, no fee is required.

Applicant does not intend to represent that any of the documents submitted herein are material prior art to this invention or that the list represents an exhaustive search of documents related to this invention.

Applicant respectfully requests that the documents submitted herein be considered and made of record in this application.

Date: July 9, 2004

Respectfully submitted,

Name: Mark J. FitzGerald  
Registration No.: 45,928  
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USPTO Form 1449 U.S. Department of Commerce Patent and Trademark Office <b>INFORMATION DISCLOSURE STATEMENT</b>				Attorney Docket No. 25436/2422		Serial No. 10/820,971		
				Applicant(s): Happe, et al.				
				Filing Date: April 8, 2004		Group: 1645		
<b>U.S. PATENT DOCUMENTS</b>								
Examiner Initial		Patent No.	Date	Name	Class	Subclass	Filing Date (if appropriate)	
	1.	5,552,279	Sept. 3, 1996	Weisburg, et al.	435	6	July 29, 1994	
	2.	5,595,871	Jan. 21, 1997	DelVecchio, et al.	435	6	Aug. 25, 1993	
	3.	5,654,418	Aug. 5, 1997	Sheiness, et al.	536	24.32	June 2, 1995	
	4.	5,656,427	Aug. 12, 1997	Hammond, et al.	435	6	Aug. 29, 1994	
	5.	5,693,467	Dec. 2, 1997	Roblin, III, et al.	435	6	May 19, 1995	
	6.	5,700,636	Dec. 23, 1997	Sheiness, et al.	435	6	Oct. 8, 1993	
	7.	5,712,090	Jan. 27, 1998	Artiushin, et al.	435	6	May 18, 1993	
	8.	5,776,694	July 7, 1998	Sheiness, et al.	435	6	July 2, 1997	
	9.	5,843,667	Dec. 1, 1998	Weisburg, et al.	435	6	March 22, 1991	
	10.	5,969,122	Oct. 19, 1999	Hammond, et al.	536	23.1	May 16, 1997	
	11.	6,110,681	Aug. 29, 2000	Ovyn, et al.	435	6		
	12.	6,482,589 B1	Nov. 19, 2002	Weisburg, et al.	435	6	May 26, 1995	
<b>FOREIGN PATENT DOCUMENTS</b>								
Examiner Initial		Document No.	Publication Date	Country	Class	Subclass	Translation	
							YES	NO
<b>OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)</b>								
	13.	Blazek, R. et al., (1990), "Fast and simple procedure for the detection of cell culture mycoplasmas using a single monoclonal antibody", <i>Journal of Immunological Methods</i> , 131:203-212.						
	14.	Collighan, R.J. et al., (1997), "Spirochaetes and other bacterial species associated with bovine digital dermatitis", <i>FEMS Microbiology Letters</i> , 156:37-41.						
	15.	Corless, C.E. et al., (2000), "Contamination and Sensitivity Issues with a Real-Time Universal 16S rRNA PCR", <i>Journal of Clinical Microbiology</i> , 38(5):1747-1752.						
	16.	Dussurget, O. et al., (1994), "Rapid, Sensitive PCR-Based Detection of Mycoplasmas in Simulated Samples of Animal Sera", <i>Applied and Environmental Microbiology</i> , 60(3):953-959.						
	17.	Eastick, K. et al., (2003), "A novel polymerase chain reaction assay to detect <i>Mycoplasma genitalium</i> ", <i>J. Clin. Pathol.: Mol. Pathol.</i> , 56:25-28.						
	18.	Harasawa, R. et al., (1993), "Detection and tentative identification of dominant mycoplasma species in cell cultures by restriction analysis of the 16S-23S rRNA intergenic spacer regions", <i>Res. Microbiol.</i> , 144:489-493.						

19.	Hopert, A. et al., (1993), "Specificity and sensitivity of polymerase chain reaction (PCR) in comparison with other methods for the detection of mycoplasma contamination in cell lines", <i>Journal of Immunological Methods</i> , 164:91-100.
20.	Kong, F. et al., (2001), "Species-Specific PCR for Identification of Common Contaminant Mollicutes in Cell Culture", <i>Applied and Environmental Microbiology</i> , 67(7):3195-3200.
21.	Loens, K. et al., (2002), "Detection of <i>Mycoplasma pneumoniae</i> in Spiked Clinical Samples by Nucleic Acid Sequence-Based Amplification", <i>Journal of Clinical Microbiology</i> , 40(4):1339-1345.
22.	Mattsson, J.G. et al., (1993), "Oligonucleotide probes complementary to 16S rRNA for rapid detection of mycoplasma contamination in cell cultures", <i>FEMS Microbiology Letters</i> , 107:139-144.
23.	McGarrrity, G.J. et al., (1986), "Comparative Studies to Determine the Efficiency of 6 Methylpurine Deoxyriboside to Detect Cell Culture Mycoplasmas", <i>In Vitro Cellular &amp; Developmental Biology</i> , 22(6):301-304.
24.	Rawadi, G. et al., (1995), "Advances in PCR-based Detection of Mycoplasmas Contaminating Cell Cultures", <i>PCR Methods and Applications</i> , 4:199-208.
25.	Sidhu, M.K. et al., (1995), "Competitor internal standards for quantitative detection of mycoplasma DNA", <i>FEMS Microbiology Letters</i> , 128:207-212.
26.	Tang, J. et al., (2000), "A polymerase chain reaction based method for detecting <i>Mycoplasma/Acholeplasma</i> contaminants in cell culture", <i>Journal of Microbiological Methods</i> , 39:121-126.
27.	Teyssou, R. et al., (1993), "Detection of mollicute contamination in cell cultures by 16s rDNA amplification", <i>Molecular and Cellular Probes</i> , 7:209-216.
28.	Uphoff, C.C. et al., (2002), "Detection of mycoplasma in leukemia-lymphoma cell lines using polymerase chain reaction", <i>Leukemia</i> , 16:289-293.
29.	Uphoff, C.C. et al., (1992), "Sensitivity and Specificity of Five Different Mycoplasma Detection Assays", <i>Leukemia</i> , 6(4):335-341.
30.	van Kuppeveld, F.J.M. et al., (1994), "Detection of Mycoplasma Contamination in Cell Cultures by a Mycoplasma Group-Specific PCR", <i>Applied and Environmental Microbiology</i> , 60(1):149-152.
31.	van Kuppeveld, F.J.M. et al., (1992), "Genus- and Species-Specific Identification of Mycoplasmas by 16s rRNA Amplification", <i>Applied and Environmental Microbiology</i> , 58(8):2606-2615.
32.	Wirth, M. et al., (1994), "Detection of mycoplasma contaminations by the polymerase chain reaction", <i>Cytotechnology</i> , 16:67-77.
33.	Yoshida, T. et al., (2002), "Quantitative Detection of <i>Mycoplasma genitalium</i> from First-Pass Urine of Men with Urethritis and Asymptomatic Men by Real-Time PCR", <i>Journal of Clinical Microbiology</i> , 40(4):1451-1455.

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

\*\*Copies of references not provided at the time of this submission.



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Brenda M. Woods

Name of Person Mailing Paper

*Brenda M. Woods*

Signature of Person Mailing Paper

**Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450**

**TRANSMITTAL LETTER**

Enclosed for filing in the above-identified patent application, please find the following documents:

1. Information Disclosure Statement;
2. Form PTO-1449;
3. Copies of Cited References; and
4. Return Post Card.

The Commissioner for Patents is hereby authorized to charge any fees to Deposit Account No. 16-0085, Reference 25436/2422. A duplicate of this transmittal letter is enclosed for this purpose.

Respectfully submitted,

Date: July 9, 2004

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